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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,767	03/17/2000	Wolfgang Kreiss	LeA 33 072	3608

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	7

DATE MAILED: 03/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/527,767	KREISS ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 1-11 and 25-26, with traverse, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's cancellation of claims 12-24 is also acknowledged and has been entered. Accordingly, claims 1-11 and 25-26 are pending and under examination.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only.

Information Disclosure Statement

3. The Information Disclosure Statement (PTO-1449) filed October 10, 2000 in Paper No. 3 is acknowledged. Reference A was not considered because neither an English translation nor a statement of relevancy was provided therefor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-11 and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has improper antecedent basis problem in reciting, "Sensor layer". Change to "A sensor layer" for proper antecedent basis.

Claims 2-11 have improper antecedent basis problem in reciting, "Sensor layer according to ... ". Change to "The sensor layer according to ..." for proper antecedent basis.

Claim 1 is vague and indefinite because it is unclear what is encompassed in reciting, "biological effects of substances".

Claim 1 is non-idiomatic and therefore indefinite in reciting, "characterized in that". See also claims 2-11.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74

(Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "matrix is a gel", and the claim also recites "agarose, polyacrylates, or a viscous solution" which is the narrower statement of the range/limitation.

Claim 4 is ambiguous in reciting, "different types of sensors" because it is unclear what is encompassed by the term "type(s)" as used in the claim.

In claim 4, "one type of sensors" should be "one type of sensor".

Claim 4 is indefinite in reciting, "able to indicate different biological effects" because it fails to recite a positive limitation in the claim. Further, it is unclear what Applicant intends to encompass in reciting, "biological effects".

Claim 5 is confusing in reciting, "sensor layer contains additions" because it is unclear what is encompassed by the term "additions" as used in the claim. See also claim 6.

Claim 8 is ambiguous in reciting, "part-layers" because it is unclear what is encompassed by the term "part-layers" as used in the claim.

Claim 8 is vague and indefinite in reciting, "it being possible for the part-layers to differ" because the term "possible" is a subjective term that lacks a comparative basis for defining its metes and bounds.

Regarding claim 8, "and/or" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "and/or"), thereby rendering the scope of the claim unascertainable.

Claim 9 is vague and indefinite because the terms "preferably" and "particularly preferably" are subjective terms that lack a comparative basis for defining their metes and bounds.

Claim 9 is ambiguous because it is unclear how the "sensor layer composition" relates to the "sensor layer" in claim 1 from which it depends. Specifically, it is unclear what is contained in the "composition" in relation to the "sensor layer".

Claim 11 is vague and indefinite because the terms "preferably" and "particularly preferably" are subjective terms that lack a comparative basis for defining their metes and bounds.

Claim 25 has improper antecedent basis problem in reciting, "Apparatus for ...". Change to "An apparatus for" for proper antecedent basis.

Claim 25 is vague and indefinite because it is unclear what is encompassed in reciting, "biological effects of substances".

Claim 25 lacks antecedent support in reciting, "the sample to be assayed".

Claim 25 is confusing in reciting, "an imaging system in whose detection zone a part or a whole of the sensor layer is located". Please clarify. Specifically, the structural and functional cooperative relationship between the elements, i.e. imaging system and detection zone, is not clearly defined.

Claim 26 is non-idiomatic and therefore indefinite in reciting, "characterized in that".

Claim 26 lacks antecedent support in reciting, "the emission of light".

Claims 26 has improper antecedent basis problem in reciting, "Apparatus according to ... ". Change to "The apparatus according to ..." for proper antecedent basis.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sachs et al. (US 5,942,409).

Sachs et al. disclose a cytosensor microphysiometer for screening and identifying biological effects or activity / inhibition of substances (see column 7, lines 45-59 and column 8). The substances are directed against urel-dependent mechanisms maintaining bacterial metabolism and viability in acidic media especially urel-dependent mechanisms of Helicobater pylori urease activation (see column 4, lines 12-65). Specifically, Sachs et al. disclose a cytosensor layer consisting of diffusion-controlling matrix such a agarose and H. pylori cells suspended therein. The cells are in aqueous diffusive contact with light addressable potentiometric pH sensor which assists in detection process. The sensor layer is perfused with buffers (balanced salt solutions), HCL and supplemented with glucose and glutamine to regulate the vitality of the sensor cells (see column 15, lines 16 to column16). The primary sensor output is in voltage and the changes of unit per time is calculated by a computer (see column 14, lines 43-63).

5. Claims 1, 3-8, and 25-26 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Zlokarnik et al. (US 5,942,409).

Zlokarnik et al. disclose a sensor layer composition for use in screening biological effects of substances, i.e. test chemicals having a putative modulator such as to cellular activity (see Abstract, column 5, line 44 to column 6, line 9, and column 7, lines 1-17). Zlokarnik et al. disclose the sensor layer or a plurality thereof, having a composition comprising cells (membrane compartments) in contact with a solid surface, fluorescent reagent or bioluminescent substrate, aqueous solution, and an indicator dye (see column 3, lines 9-20, column 9, lines 42-56, and column 13, lines 47-65). Zlokarnik et al. disclose different types of fluorescent monitoring systems including imaging systems (see column 16, line 46 to column 17, lines 25). Fluorescence resonance energy transfer (FRET) exemplifies a way to monitor activity inside the cells, such as with reporter gene system (see column 18, lines 8-43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al. (US 5,942,409).

Sachs et al. disclose a cytosensor microphysiometer for screening and identifying biological effects or activity / inhibition of substances (see column 7, lines 45-59 and column 8). The substances are directed against urel-dependent mechanisms maintaining bacterial metabolism and viability in acidic media especially urel-dependent mechanisms of Helicobater pylori urease activation (see column 4, lines 12-65). Specifically, Sachs et al. disclose a cytosensor layer consisting of diffusion-controlling matrix such a agarose and H. pylori cells suspended therein. The cells are in aqueous diffusive contact with light addressable potentiometric pH sensor which assists in detection process. The sensor layer is perfused with buffers (balanced salt solutions), HCL and supplemented with glucose and glutamine to regulate the vitality of the sensor cells (see column 15, lines 16 to column16). The primary sensor output is in voltage and the changes of unit per time is calculated by a computer (see column 14, lines 43-63).

Sachs et al. differ from the instant invention in failing to disclose the concentration, i.e. 2-8 ml or 3-5 ml, as recited in claim 9, and optical density of cell suspensions, i.e. 0.6 - 1.4 at 660 nm as recited in claim 10, present in an amount of sensor layer composition, i.e. 50 ml as recited in claim 9. Further, Sachs et al. differ in failing to disclose the preferred thickness of the sensor layer, i.e. 0.1-10 nm, 0.5-3 mm, and 0.5-0.8 mm as recited in claim 11.

However, the amount of layer composition, sensor layer concentration in proportion to the amount of cells present, and acceptable optical density of a plurality of cells in a composition, i.e. 1.5 x10% bacterial cells, 10 mM glucose and 1mM glutamine,

etc. as additives, are all result effective variables which the Sachs et al. has shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 9-11 are for any particular purpose or solve any stated problem and the prior art teaches that sensors having membrane or film compositions may have different acceptable values dependent upon the method or purpose it is used, concentrations and parameters appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by Sachs et al. by normal optimization procedures known in the art.

7. No claims are allowed.

Remarks

8. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Hessel et al. (US 6,048,735) disclose sensor laminates for detecting target molecules.

Clark et al. (US 5,194,133) disclose a sensor device having a sensor layer consisting of agarose, polyacrylate polymer gel, and biological material such as lectin, enzyme, lipid, etc.

Peitzsch et al. (Applied and Environmental Microbiology, February/ 1998) teach Alcaligenes eutrophus as bacterial chromate sensor.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R Gabel whose telephone number is (703) 305-9297. The examiner can normally be reached on Monday-Thursday 6:00 AM to 3:30 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
March 23, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/24/02